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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,009	04/28/2005	Mirza Kamran Baig	1926-00105	1704

26753 7590 10/30/2007

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EXAMINER	
RYCKMAN, MELISSA K	
ART UNIT	**PAPER NUMBER**
3773	
MAIL DATE	**DELIVERY MODE**
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,009	BAIG, MIRZA KAMRAN	
	Examiner	Art Unit	
	Melissa Ryckman	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to arguments and claims received 8/27/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-20, 22-24 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Schatz et al. (US 6027509).

Regarding Claim 16, Schatz teaches a device for retrieval of a foreign body from a vessel of a patient, said device comprising: a flexibly resilient central shaft (110, it is noted that all materials comprise some level of flexibility) having an axial channel capable of receiving a guidewire therein (it is noted that since central shaft 110 comprises an inflation lumen, it is capable that a guidewire may be disposed in the lumen); balloon support means (46) extending from said central shaft and having a free end spaced therefrom (fig. 4); and inflatable balloon means (38) provided at said free end and arranged to expand inwardly towards said central shaft upon inflation (fig. 2); whereby in use said device is positioned such that a foreign body to be retrieved is located between said free end and said central shaft, and said balloon means is subsequently inflated to bear against the foreign body and hold it against said central

shaft, such that the combined foreign body and device can be withdrawn from the vessel (figs. 3-6).

Regarding Claim 17, Schatz teaches the device as claimed in claim 16, wherein the foreign body is an undeployed stent (104); and whereby in use said balloon means is inflated to bear against the outer circumference of the stent and hold the stent against said central shaft (fig. 6).

Regarding Claim 18, Schatz teaches the device as claimed in claim 17, wherein said inflatable balloon means (38) is arranged so as in use to bear against the stent at two or more spaced locations around the circumference thereof (fig. 2).

Regarding Claim 19, Schatz teaches the device as claimed in claim 16, wherein said central shaft (110) is flexibly resilient (108) and has a tip extending beyond said free end of said balloon support means (fig. 4).

Regarding Claim 20, Schatz teaches the device as claimed in claim 16, wherein said inflatable balloon means (38) is generally annular (fig. 2).

Regarding Claim 22, Schatz teaches the device as claimed in claim 19, wherein said central shaft (110) is generally cylindrical, having a uniform diameter along most of its length (fig. 3), and a short tapering section towards its tip (108).

Regarding Claim 23, Schatz teaches the device as claimed in claim 16, further comprising a hub at an end of said central shaft (22) distal from said inflatable balloon means, it is noted that the distal-most end of central shaft 22 is a hub

Regarding Claim 24, Schatz teaches the device as claimed in claim 23, wherein said hub has a port (distal-most end of lumen 24) in fluid communication with said inflatable balloon means (38) to enable inflation thereof by injection of an inflation fluid.

Regarding Claim 28, Schatz teaches the device as claimed in claim 16, said device being adapted for delivery into and recovery from a vessel by means of a guiding catheter (see entire document, for example Column 2, proximate lines 53-59).

Regarding Claim 29, Schatz teaches the device as claimed in claim 16, further comprising a guiding catheter for delivery of said device into a vessel, and subsequent recovery of said device therefrom (see entire document, for example Column 2, proximate lines 53-59).

Regarding Claim 30, Schatz teaches a device for retrieval of an undeployed stent from a vessel of a patient, which device comprises: a central shaft (110) having an axial channel for receiving an angioplasty guidewire therein; balloon support means (46) extending from said central shaft and having a free end (42) spaced therefrom; and inflatable balloon means (38) provided at said free end and arranged to expand inwardly towards said central shaft upon inflation; whereby in use the device is positioned such that an undeployed stent is located between said free end and said central shaft, and said balloon means is subsequently inflated to bear against the outer circumference of the stent and hold the stent against said central shaft, such that the combined stent and device can be withdrawn from the vessel (figs. 3-6).

Claims 16 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Schatz (US 5868753), hereinafter "Schatz '753".

Regarding Claim 16, Schatz '753 teaches a device for retrieval of a foreign body from a vessel of a patient, said device comprising: a flexibly resilient central shaft (36, it is noted that all materials comprise some level of flexibility) having an axial channel for receiving a guidewire therein (42); balloon support means (22) extending from said central shaft and having a free end spaced therefrom (1); and inflatable balloon means (50) provided at said free end and arranged to expand inwardly towards said central shaft upon inflation (fig. 5); whereby in use said device is capable of being positioned such that a foreign body to be retrieved is located between said free end and said central shaft, and said balloon means is subsequently inflated to bear against the foreign body and hold it against said central shaft, such that the combined foreign body and device can be withdrawn from the vessel.

Regarding Claim 21, Schatz '753 teaches the device as claimed in claim 16, wherein said balloon support means is a generally cylindrical sleeve extending axially of the central shaft (fig. 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatz in view of Bosley Jr. (US 4930496)

Schatz teaches all limitations of preceding claims 16, 23 and 24, but fails to teach wherein said port is adapted to receive a syringe from which the inflation fluid is to be delivered. Bosley Jr. teaches an intraluminal catheter for inflating a balloon, wherein the device includes a hub designed to be connected to an appropriate inflation fluid which may be contained within a syringe so that the fluid may be injected into and removed from the balloon to allow for selective inflation and deflation of the balloon. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Schatz with a hub designed to be connected to an appropriate inflation fluid which may be contained within a syringe as taught by Bosley Jr. so that the fluid may be injected into and removed from the balloon to allow for selective inflation and deflation of the balloon.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schatz in view of Tsugita et al. (US 5910154).

Schatz teaches all limitations of preceding claims 16, 23 and 24, but fails to teach wherein said inflation fluid is of radiographic contrast. Tsugita teaches an intraluminal catheter for inflating a balloon, wherein the said inflation fluid is of radiographic contrast in order to allow the surgeon to accurately image the device during use. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Schatz with radiographic contrasting inflation fluid as taught by Tsugita in order to allow the surgeon to accurately image the device during use.

Claim 27 rejected under 35 U.S.C. 103(a) as being unpatentable over Schatz. Schatz teaches all limitations of preceding dependent claims 16, 23 and 24, but fails to teach wherein inflation of said inflatable balloon means is effected by the injection of a volume of inflation fluid in the range of from 2 to 5 ml. The device of Schatz performs the same function as that of the present application in the same manner, and further discloses inflating the inflation members sufficiently to grip the stent structure. Since applicant has not disclosed that this specific range provides any advantage over any other workable ranges, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose the volume of inflation fluid to be in the range from 2 to 5 ml since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233

Response to Arguments

Applicant's arguments filed 8/27/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The central shaft 110 in Schatz 1 is not a feature of the stent
- Schatz 1 does not fully disclose or perform the same function as the features of the claims (page 7 arguments 8/27/07)
- The central shaft 36 in Schatz 2 is not an element of the stent retrieval catheter.

The examiner respectfully diagrees with the applicant. The examiner would like to point out to the applicant that the claim reads "a flexibly resilient central shaft having an axial channel for receiving a guidewire therein", Schatz 1 and 2 teach this limitation. The device of Schatz teaches the structure of the current applicant, the applicant is urged to include structural limitations regarding the functionality.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER